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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,492	12/03/2001	Lawrence R. Toll	10454-017001	3231
26161	7590	03/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/006,492

**Applicant(s)**

TOLL ET AL.

**Examiner**

Marianne P. Allen

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-141 is/are pending in the application.
- 4a) Of the above claim(s) 41-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72-141 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 40-141 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/18/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's arguments filed 12/18/03 have been fully considered but they are not persuasive.

Claims 1-40 have been cancelled and claims 72-141 have been newly added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 4-5, 11-18, 21-28, 31, 34, and 39 under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (**Protein Engineering**, 12(1):3-9, 1999) is withdrawn in view of cancellation of the claims. This art may be reapplied if the new matter rejection is overcome.

### ***Election/Restrictions***

Claims 41-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 10.

### ***Oath/Declaration***

The new oath or declaration is noted.

### ***Claim Rejections - 35 USC § 101/112***

Claims 72-141 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claims 72-141 are newly introduced claims. No basis in the specification has been pointed to for these methods (claims 72-140) or computer readable media (claim 141) and none is apparent.

In particular, there does not appear to be basis for general statistical models or general topological patterns. A match Hidden Markov Model (mHMM) does not provide support for these more general concepts.

Applicant is requested to point to page and line number in the specification in support of the steps and particular limitations of each newly presented claim.

Should this new matter rejection be overcome, the claims would be subject to an enablement rejection similar to that set forth in the prior Office action. Briefly, the claims as written are not enabled because they fail to include critical steps for performing the method such that one of ordinary skill in the art would get a concrete, tangible, and useful result. In addition, it would constitute undue experimentation to develop models other than a hidden Markov model to compare sequences because the specification fails to disclose or suggest other implementations that could be used to practice the claimed method. One of ordinary skill in the art would be required to practice experimentation beyond what is routine to develop and validate other models.

Claims 72-141 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 72-106 are directed to a method for identifying biopolymer sequences comprising constructing a model, comparing the topological patterns and identifying biopolymer sequences.

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Claims 107-140 are directed to a method for identifying biopolymer sequences comprising constructing a model, comparing the topological patterns, identifying a similarity or dissimilarity, and identifying biopolymer sequences.

As written, the claimed method recites only data manipulation steps and do not provide a concrete, tangible, and useful result. The claims provide no criteria for identifying biopolymers (i.e. if they are similar to the model identify them as being of interest) nor do the claims provide a tangible, concrete, or useful reason to identify the sequences (i.e. the method is intended to find sequences similar to something known to be useful because these similar sequences would be expected to be similarly useful.) It is noted that claims 72-106 do not make clear how the comparing step results in the identification step. A comparison alone would not seem to result in identification of biopolymers that are tangible, concrete, and useful. Likewise, claims 107-141 look for both similarity and dissimilarity and do not discriminate. Again, identifying a similarity and/or dissimilarity alone would not seem to result in identification of biopolymers that are tangible, concrete, or useful. In addition, it is unclear whether the model recited in the claim is intended to be data (a fixed model, data structure, or statistical description of the sequences) or computer executable code that uses the model and has specific functionality.

Claim 141 is directed to computer readable medium comprising a statistical model. This is considered to be directed to medium containing data which is non-statutory. If applicant intended this claim to be directed to a computer readable medium containing computer executable code with specific functionality, the language used does not set this forth.

Applicant is again directed to MPEP 2106 as well as the Trilateral Project WM4 Report on Comparative Study on Protein 3-Dimensional (3-D) Structure Related Claims at: [www.uspto.gov/web/tws/wm4/wm4\\_3d\\_report.htm](http://www.uspto.gov/web/tws/wm4/wm4_3d_report.htm).

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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*Marianne P. Allen*

Marianne P. Allen

Primary Examiner

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*3/18/04*

mpa

March 18, 2004